



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Examiner: Misook Yu
Donald Durden) Art Unit: 1642
Serial No. 09/870,379) Response to Paper No: 8
Filed: May 30, 2001)
For: "Compositions and Methods)
for Identifying Agents)
Which Modulate PTEN)
Function and PI-3 Kinase)
Pathways")

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DECLARATION OF DONALD L. DURDEN

I, Donald L. Durden, hereby declare that:

1. I am the inventor of the invention described and claimed in U.S. Patent Application Serial No. 09/870,379, (the '379 application).

2. I have read and am familiar with the contents of the Official Action dated January 15, 2003 in the '379 application. I note that the Examiner has rejected claims 80-82 under 35 U.S.C. §112, first paragraph for an alleged lack of written description and inadequate enablement. The Examiner has also rejected claims 80 and 81 under 35 U.S.C. §102(a) as allegedly anticipated by Hu et al. as evidenced by Jiang et al. or Oikawa et al. The purpose of this declaration is to provide evidence of conception of the claimed invention in this country prior to the March, 2000, which I understand to be the effective publication date of the Hu et al. PNAS reference. The Declaration will also provide evidence of a diligent reduction to practice of the invention immediately following conception of the same.

3. I conceived of methods for treating aberrant angiogenesis by targeting PTEN as a way of overcoming the problems associated with aberrant expression of this protein in tumor promoted angiogenesis. My original conception of this invention is set forth in Exhibit A which is an invention

disclosure form submitted to the Indiana University Advanced Research and Technology Institute. This submission predates the publication both the Hu et al. and Jiang et al. references.

4. As evidence of a diligent reduction to practice of the present invention, submitted herewith is a copy of a Grant proposal for a competitive renewal of grant RO1 CA75637 submitted to the National Institutes of Health (Exhibit B). This application describes methods of using PI-3 kinase inhibitors for the treatment of aberrant angiogenesis associated with cancer. See page 18. As further evidence of a diligent reduction to practice of the present invention, submitted herewith are copies of two US Provisional Applications, 60/208,437 (Exhibit C) and 60/274,167 (Exhibit D) filed May 20, 2000 and March 8, 2001 respectively. The '379 application claims priority to both of these provisionals. The Examiner's attention is drawn to Example IV which provides Figures 15, 16 and 17 and the disclosure relating to the same in the '167 application. These data reveal an effective inhibition of tumor induced angiogenesis in LY294002 nude mouse model. Conception of the subject matter described in Exhibits A, B, C and D occurred in the United States. The experiments described in Exhibits B, C and D were performed in the United States.

5. I was diligent in reducing the invention to practice, including the period from just prior to February 15, 2000 until the invention was subsequently reduced to practice as set forth in paragraph 4 above. On information and belief, March 2000 is the earliest publication date ascribable to the Hu et al. manuscript.

6. All of the experiments, the results of which are presented in the Exhibits attached to this Declaration, were performed by me or under my direction and supervision.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued thereon.

6-11-2003

DATE

Donald L. Durden

Donald L. Durden